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DEVICE LABELLING AND IMPORT

Sponsors around the world increasingly select Australia and New Zealand to conduct medical device trials. Among the myriad of reasons:

- **Tax benefits** and **favorable currency exchange rates**.
- **FDA (and other regulatory bodies)** favorably regard Australasia's process-driven approach to study conduct.
  - Data from Australasian trails is generally deemed acceptable by other regulatory bodies
- **Standard of Care** matches (or exceeds) that of others in the G8.
- **Australia's Therapeutic Goods Authority (TGA)** and New Zealand's Medsafe are both highly involved with robust guidelines around study parameters.
- **Excellent sites and world-class physicians** located in the region.

Among all its bona fides, one hurdle often derails sponsors: **Device Labelling and Import.**

LABELLING:

Shipping medical devices into Australia and New Zealand demands strict adherence to Regulatory guidelines and national quarantine import requirements as well as compliance with the TGA and MedSafe guidelines. Successful importation of any device used to conduct your trial largely relies on the very specific labelling used to describe the device and its intended use.

For medical devices, a manufacturer must apply a conformity assessment procedure as defined for an investigational device under Regulation 3.10 of the Therapeutic Goods (Medical Devices) Regulations 2002.

In practice, this means your medical device entry application must be supported by:

1. The application of ISO 13485 – Medical Devices, Quality Management Systems Requirements for Regulatory Purposes, and

2. Certification by an independent third party

Start-up medical device companies do not usually have third party validation for their quality management system prior to commencing their pilot study. In this case, sponsors should ensure device component manufacturers can substantiate compliance by providing documentation during Ethics Committee submission (HREC). Some aspects related to construction or manufacturing of medical devices are scrutinized for safety and other considerations by this body.

IMPORTING:

Some of the barriers to the import of investigational medical devices include:

- Right to import: Only an Australian or New Zealand local entity can import investigational products or devices into their region. A Local Sponsor can assist.
- Customs – does your device require a license or permit to import or to use?
  A Local Sponsor can assist
- Biosecurity – do any of your components have a biological origin?
- Storage and transport – do your products or devices require temperature control or monitoring during transport of storage? PCRG's import partners can assist.